

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 16-0458V

Filed: April 18, 2017

Unpublished

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BETTY D. BACKMAN,

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Petitioner,

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v.

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SECRETARY OF HEALTH

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AND HUMAN SERVICES,

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Respondent.

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*William P. Ronan, III, The Ronan Law Firm, Overland Park, KS, for petitioner.*

*David G. Cutler, U.S. Department of Justice, Washington, DC, for respondent.*

### **RULING ON ENTITLEMENT**<sup>1</sup>

**Dorsey**, Chief Special Master:

On April 11, 2016, Betty D. Backman (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered various shoulder injuries as a result of receiving the influenza (“flu”) vaccine on November 12, 2014. Petition at 1-5. The case was assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

### **I. Summary of Procedural History**

On May 25, 2016, the staff attorney assigned to manage this case on behalf of the undersigned held the initial telephonic status conference. William Ronan appeared for petitioner. David Cutler appeared for respondent. At the conference, respondent requested that petitioner file primary care records from two years prior to vaccination, as

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<sup>1</sup> Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

well as any medical records showing she complained of or sought treatment for arm pain between the date of vaccination and her first evaluation on February 20, 2015.<sup>3</sup> Respondent also requested that petitioner file any available records related to a rotator cuff tear discovered in 2003.<sup>4</sup> See Sched. Order, issued May 26, 2016 (ECF No. 9).

On July 20, 2016, petitioner filed primary care records for the period beginning two years prior to vaccination, and for the entire year of 2003. She also filed an affidavit explaining her delay in seeking treatment.<sup>5</sup>

On September 19, 2016, respondent file a Rule 4(c) Report recommending that entitlement under the Vaccine Act be denied. Rule 4(c) Report ("Report"), filed Sept. 19, 2016 (ECF No. 12). In respondent's view, petitioner's claim fell short in several areas. Specifically, petitioner failed to "demonstrate that she received the November 12, 2014 flu vaccination in her left arm." *Id.* at 6. She also failed to "provide evidence that the vaccine in fact caused her left shoulder pain." *Id.* On this point, respondent argued that petitioner had not provided a "medical theory linking her vaccination and her alleged injury [or] ... any evidence of a logical sequence of cause and effect showing the vaccine was the reason for the claimed shoulder injury." *Id.* 6-7. Furthermore, "petitioner's claim of a temporal association between her vaccination and her left arm pain" was unsupported by the record. *Id.* at 7. Petitioner had not carried her burden of proving causation-in-fact under *Althen v. HHS*, 418 F.3d 1274 (Fed. Cir. 2005).

In a footnote, respondent also argued that petitioner would not meet proposed criteria for shoulder injury related to vaccine administration ("SIRVA").<sup>6</sup> Report at 6 n.4. This was because petitioner had not established that the vaccination was administered to her left arm or showed that the onset of her pain was within 48 hours. *Id.* She also "had evidence of calcification of a tendon in the left rotator cuff [suggestive of] a chronic preexisting injury in her left shoulder." *Id.* (citing Pet'r's Ex. 3 at 4).

On October 12, 2016, the assigned staff attorney convened a status conference to discuss the issues raised by respondent's Report and to convey the undersigned's preliminary views and recommendations based on her review of the evidence. See Sched. Order, issued Oct. 14, 2016 (ECF No. 13).

The staff attorney began by informing the parties that the undersigned disagreed with respondent's argument that vaccine causation is essentially foreclosed because of the cited evidence suggesting "a chronic preexisting injury in her left shoulder." *Id.* (citing Report at 6 n.4). While the undersigned agreed that the presence of calcification

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<sup>3</sup> See Pet'r's Ex. 2 at 42-44. Respondent expressed concern about the lack of medical records reflecting complaint of or treatment for shoulder and/or arm pain during this three-month period.

<sup>4</sup> See Pet'r's Ex. 2 at 49 (noting "2003 rotator cuff tear confirmed by MRI").

<sup>5</sup> Pet'r's Exs. 5 (records) and 6 (affidavit).

<sup>6</sup> SIRVA has since been added to the Vaccine Injury Table, effective for petitions filed beginning on March 21, 2017. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017 (delaying the effective date of the final rule until March 21, 2017).

suggests a chronic condition, based on her experience, the cause of calcification in tendons is unknown. *Id.* In this case, the calcification could be from an unrelated preexisting condition; it could be the result of the vaccine injection partially tearing the rotator cuff; or petitioner may have had chronic issues made worse by the vaccination. *Id.* However, without an earlier MRI study to serve as a baseline, the cause cannot be known. *Id.*

With regard to petitioner's delay in reporting her symptoms to her doctor, the undersigned's personal experience, and her experience derived from reviewing SIRVA cases, had shown that patients do not always report every ailment when they are seen by a doctor for a different acute problem. *Id.* The undersigned believed this was the case here. *Id.*

Finally, as to respondent's assertion that petitioner had not yet "shown that she had the onset of pain within 48 hours of her vaccination," the undersigned considered petitioner's affidavit to be credible evidence on the question of onset. *Id.*

The staff attorney then advised the parties that the undersigned believed a fact hearing could be helpful in this case. Such a hearing would allow petitioner to testify about the circumstances of her vaccination and to answer questions about her receipt of the vaccine. It would also give her an opportunity to discuss why she did not complain to or seek treatment from a doctor earlier. As an alternative, the undersigned urged the parties to consider engaging in tentative settlement discussions based on litigative risk.

At the conclusion of the conference, the parties requested a period of 30 days in which to confer with each other about possible next steps. *Id.* Additionally, petitioner's counsel agreed to work to obtain and file updated primary care records for treatment after November 2015; any physical therapy records not already submitted; and records of any MRI study of the left shoulder performed prior to September 11, 2015.<sup>7</sup> *Id.* at n.3.

On November 15, 2016, petitioner filed a status report to request a fact hearing be scheduled. (ECF No. 14). Petitioner also filed updated primary care records through October 14, 2016.<sup>8</sup> Additionally, in an amended status report, petitioner stated that all physical therapy records had been submitted, and that "other than the MRI identified in the Petition filed herein, Petitioner has never had any other MRIs of her left shoulder." (ECF No. 16).

Based on the parties' input, the undersigned scheduled a fact hearing for February 28, 2017, in Washington, D.C. See Pre-Hearing Order, issued Dec. 16, 2016 (ECF No. 21). Petitioner filed a witness list on February 10, 2017 (ECF No. 23), and an amended list on February 15, 2017 (ECF No. 25), containing a general description of the expected testimony of each witness. Respondent did not plan to call any witnesses.

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<sup>7</sup> See Pet'r's Ex. 2 at 7.

<sup>8</sup> Pet'r's Ex. 7.

## II. Fact Hearing

The undersigned held the fact hearing as planned, with petitioner and three other lay witnesses testifying via videoconference.<sup>9</sup> At the conclusion of the proceeding, the undersigned informed the parties that she intended to issue a ruling from the bench as to the contested facts of this case. See Hearing Transcript (“Tr.”), filed Mar. 15, 2017 (ECF No. 29), at 109. Both parties agreed to this proposed action. Tr. at 110.

After a short recess, the undersigned returned and read her ruling into the record. Tr. at 110-13. With regard to the site of injection, the undersigned found that petitioner received the flu shot on November 12, 2014, and that it was administered to her left arm. Tr. at 110. With regard to the onset of symptoms, the undersigned found that petitioner had pain “almost immediate[ly] and before she left the pharmacy.” Tr. at 110-11. And finally, the undersigned found that petitioner’s apparent lack of timely complaint to her doctor could plausibly be explained by the presence of a more pressing health issue for which she was seeking treatment—an acute bronchial illness. In any event, petitioner’s delay in reporting is not fatal to her claim.<sup>10</sup> Tr. at 111.

Having resolved the pertinent factual issues, the undersigned then found that petitioner had met all of the criteria for a SIRVA.<sup>11</sup> Tr. at 112-13.

## III. Conclusion

On March 17, 2017, the undersigned afforded the parties 14 days in which to file, or request to file, additional relevant evidence in this matter. See Order, issued Mar. 17, 2017 (ECF No. 30). The order advised the parties that after 14 days, the evidence in

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<sup>9</sup> A fourth witness was planned; however, the parties and the undersigned agreed that his testimony would be cumulative. Tr. at 109.

<sup>10</sup> However, the deficiencies identified by respondent are relevant to the value of the claim. Tr. at 113.

<sup>11</sup> Although petitioner’s claim was filed before SIRVA was added to the Vaccine Injury Table, and thus cannot be found to be a SIRVA Table injury, the undersigned’s findings were informed by the criteria used to evaluate such claims. See *supra* note 6. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA); see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

this matter would be closed and a ruling on entitlement would issue. No additional evidence, or request to file evidence, was received.<sup>12</sup>

**In view of the submitted evidence, including the medical records, credible witness testimony, and findings of fact, the undersigned finds petitioner entitled to Vaccine Act compensation.**

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**  
Nora Beth Dorsey  
Chief Special Master

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<sup>12</sup> Petitioner previously was ordered to file certain chiropractic records by the same deadline of March 31, 2017. See Post-Hearing Sched. Order, issued Mar. 1, 2017 (ECF No. 27). Petitioner filed the records on March 22, 2017, as exhibit 8.